

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA and
STATE OF FLORIDA *ex rel.* OMNI
HEALTHCARE, INC.,

Plaintiffs,

v.

STEWARD HEALTH CARE SYSTEM
LLC; et al.,

Defendants.

Civil Action No. 3:21-CV-0870-S

**UNITED STATES' STATEMENT OF INTEREST
REGARDING THE STEWARD DEFENDANTS'
MOTION TO DISMISS THE AMENDED COMPLAINT**

BRIAN M. BOYNTON
PRINCIPAL DEPUTY ASSISTANT
ATTORNEY GENERAL

Jamie Ann Yavelberg
David B. Wiseman
David G. Miller
Attorneys, Civil Division
U.S. Department of Justice
175 N Street N.E.
Washington, D.C. 20002
Telephone: 202-305-3231
Email: David.G.Miller@usdoj.gov

LEIGHA SIMONTON
UNITED STATES ATTORNEY

Richard J. Guiltinan
Assistant United States Attorney
Texas Bar No. 24074332
1100 Commerce Street, Third Floor
Dallas, Texas 75242
Telephone: 214-659-8600
Facsimile: 214-659-8807
Email: richard.guiltinan@usdoj.gov

The United States respectfully submits this Statement of Interest pursuant to 28 U.S.C. § 517 to address two arguments in the Steward Defendants' Motion to Dismiss. ECF Nos. 79–80. Specifically, the United States contends that the causation standard under the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7(b), and the False Claims Act (FCA), 31 U.S.C. §§ 3729–33, does not require a showing that the kickback was a but-for cause of the submission of the false claim. Second, the United States contends that the *qui tam* provisions of the FCA do not violate the United States' Constitution.

The United States submits this statement of interest to ensure the correct interpretation of these two legal issues but does not take a position on any other arguments or issues raised in Defendants' Motion and defers to the Court as to whether Relator's allegations satisfy the correct pleading standards.

I. The United States' Interest.

Although the United States has not intervened in this *qui tam* action, it remains the real party in interest, entitled to the majority of any recovery that the Relator may obtain on the United States' behalf. *See* 31 U.S.C. § 3730(d); *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 934–35 (2009). The United States has a substantial interest in ensuring the correct application of the FCA because it is “the Government’s primary litigative tool for combatting fraud” against the public fisc. *United States ex rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th 727, 732 (5th Cir. 2023) (quoting S. Rep. 99-345, reprinted in 1986 U.S.C.C.A.N. 5266).

The United States likewise has an interest in ensuring the correct interpretation of the AKS because that statute plays a critical role in safeguarding the integrity of medical

care paid for by Government health care programs. The AKS makes it a crime to “knowingly and willfully offer[] or pay[] any remuneration” in order to induce the recipient to “purchase, . . . order, or arrange for or recommend purchasing, . . . or ordering” goods or services “for which payment may be made in whole or in part under a federal health care program.” 42 U.S.C. § 1320a-7b(b)(2). In addition to criminal penalties, the AKS provides that “a claim that includes items or services resulting from” an AKS violation is “false or fraudulent” under the FCA. *Id.* § 1320a-7b(g).

II. AKS Framework and Background.

The AKS helps to protect the integrity of medical care by establishing that the government will pay only for items or services from providers who lack potential financial conflicts. Courts have long held that claims seeking reimbursement for items or services for which a kickback was offered or solicited are false or fraudulent under the FCA, because “[t]he Government does not get what it bargained for when a defendant is paid . . . for services tainted by a kickback.” *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) (citation omitted), abrogated on other grounds by *Universal Health Servs., Inc. v. United States*, 579 U.S. 176 (2016).

In 2010, Congress amended the AKS to state expressly that “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of” the FCA. 42 U.S.C. § 1320a-7b(g). This amendment added a more direct way of establishing FCA liability for AKS violations. A sponsor explained that the amendment was meant to “strengthen[] whistleblower actions based on medical care kickbacks.” 155 Cong. Rec. S10,853 (daily ed. Oct. 28, 2009) (Sen. Kaufman). The

amendment would clarify, the sponsor stated, “that all claims resulting from illegal kickbacks are ‘false or fraudulent,’ even when the claims are not submitted directly by the wrongdoers themselves.” *Id.*; *see United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 333 (S.D.N.Y. 2014) (discussing this legislative background).

III. The Steward Defendants Misstate the Causation Standard Under the AKS.

The Steward Defendants assert that Relator’s complaint should be dismissed because it failed to plead causation under the AKS. ECF No. 80 at 8–11. In making this argument, Defendants assert that the phrase “resulting from” in 42 U.S.C. § 1320a-7b(g) means that “[t]o plead causation, a relator must allege that but for the AKS violation, the defendant would not have submitted claims to the government for reimbursement.” *Id.* at 10. The United States respectfully submits that this standard—which has not been adopted by the Fifth Circuit—is incorrect because it is inconsistent with the structure and purpose of the AKS. *See United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 98 (3d Cir. 2018) (rejecting “but for” standard and noting that sufficient link is established if “one of [defendant’s] claims sought reimbursement for medical care that was provided in violation of the [AKS]”); *Kester*, 41 F. Supp. 3d at 332 (rejecting “but for” causation standard because “there is no indication in either the law itself or the legislative history that Congress intended to narrow the scope of ‘falsity’ under the FCA when it amended the AKS to add Section 1320a–7b(g)”).

As an initial matter, the Court need not—and so should not—reach this issue because it does not have to determine the proper standard for causation under the AKS at the motion-to-dismiss stage. *See United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F.

Supp. 2d 654, 665 (S.D. Tex. 2013), *aff'd sub nom. United States ex rel. Parikh v. Brown*, 587 F. App'x 123 (5th Cir. 2014) (“As a matter of pleading standards, [the Fifth Circuit in] *Grubbs* establishe[d] that Relators need not identify particular claims resulting from the kickback scheme.” (citing *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). At the pleading stage, the Court need only determine whether a relator has pleaded “particular details of a scheme to offer kickbacks in order to induce referrals, coupled with reliable indicia leading to a strong inference that claims based on such referrals were actually submitted.” *Id.* at 667 (citing *Grubbs*, 565 F.3d at 190); *see also United States ex rel. Everest Principals, LLC v. Abbott Labs., Inc.*, 622 F. Supp. 3d 920, 933 (S.D. Cal. 2022) (declining to resolve dispute over Section 1320a-7b(g)’s causation requirement where allegations sufficient at pleading stage to “adequately establish[] a ‘link’ between the kickback and the claim for reimbursement”).

Though this Court need not reach this causation issue, the majority of courts have rejected but-for causation under the AKS. *See Greenfield*, 880 F.3d at 98; *United States ex rel. Hueseman v. Pro. Compounding Centers of Am., Inc.*, 664 F. Supp. 3d 722, 741 n.4 (W.D. Tex. 2023) (“This Court is neither bound nor persuaded by the Eighth Circuit’s reasoning, which has been rejected by numerous courts.”); *United States ex rel. Fitzer v. Allergan, Inc.*, No. 1:17-CV-668-SAG, 2022 WL 3599139, at *10 (D. Md. Aug. 23, 2022); *Kuzma v. Northern Ariz. Healthcare Corp.*, 607 F. Supp. 3d 942, 957 (D. Ariz. 2022); *United States ex rel. Schroeder v. Medtronic, Inc.*, No. 17-2060-DDC-KGG, 2021 WL 4168140, at *23–24 (D. Kan. Sept. 14, 2021); *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-CV-3003, 2021 WL 101193, at *10–11 (D. Minn. Jan.

12, 2021); *United States v. Teva Pharms. USA, Inc.*, No. 13 Civ. 3702 (CM), 2019 WL 1245656, at *23 (S.D.N.Y. Feb. 27, 2019); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-CV-10601-IT, 2018 WL 1996829, at *6 (D. Mass. Apr. 27, 2018); *but see United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052–53 (6th Cir. 2023); *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 836 (8th Cir. 2022).

There are numerous reasons to reject but-for causation in the context of false claims arising from violations of the AKS. As one court observed in rejecting the *Cairns* causation analysis, the Eighth Circuit failed to consider powerful “contextual indication[s]” that Section 1320a-7b(g)’s causation standard is *not* but-for causation. *Fitzer*, 2022 WL 3599139, at *10. In addition, the AKS contains its own nexus requirement: Remuneration can support liability when it is solicited or received “in return for,” or offered or paid with the intent “to induce,” the provision of items or services or referrals to provide them. 42 U.S.C. § 1320a-7b(b)(1), (2). As its plain language makes clear, that standard does not limit AKS liability to situations where the desired outcome of the kickbacks actually materializes, much less where the kickback is the but-for cause of the outcome. *See Parikh*, 977 F. Supp. 2d at 665.

The limitation imposed by a “but for” causation standard would also be inconsistent with the AKS’s animating principle, namely that financial conflicts make it impossible to trust a provider’s judgment—whether or not the conflicts can be shown to have actually altered the provider’s treatment choices. There is no discernible basis to believe that Congress, having imposed criminal liability for AKS violations *without* requiring but-for causation, meant to require that heightened showing to impose civil liability under the FCA

for claims rendered false by AKS violations. *See Greenfield*, 880 F.3d at 96. Beyond its inconsistency with the basic purpose of the AKS, such a standard would significantly complicate the litigation of FCA cases based on AKS violations, requiring extensive efforts to disentangle the motivations of treating physicians (who may not even be among the defendants) for every treatment decision or referral at issue (often numbering in the hundreds or thousands). And it would be inconsistent with the legislative history of § 1320a-7b(g), which makes clear that Congress enacted that provision to “strengthen[] whistleblower actions based on medical care kickbacks.” 155 Cong. Rec. S10,853.

These important “contextual” factors strongly suggest that Section 1320a-7b(g) does not impose a but-for standard. *See Burrage v. United States*, 571 U.S. 204, 212 (2014). There is a much more natural interpretation of “resulting from” in that provision. Remuneration can support liability under the AKS when it is solicited or received “in return for,” or offered or paid with the intent “to induce,” referrals or the provision of items or services. 42 U.S.C. § 1320a-7b(b)(1), (2). When the intended result of a kickback occurs, it makes sense to conclude that it “result[ed] from” the kickback within the meaning of § 1320a-7b(g), without an additional showing about what might have occurred absent the kickback.

Again, the Court need not resolve this statutory dispute here. The Fifth Circuit has held that Rule 9(b) “is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act.” *Grubbs*, 565 F.3d at 190. Under binding Fifth Circuit precedent, a relator may survive a motion to dismiss “by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference

that claims were actually submitted.” *Id.* Thus, the Court need not determine the applicable standard for AKS causation at the motion-to-dismiss stage.

IV. The *Qui Tam* Provisions of the FCA Are Constitutional.

The Steward Defendants make a cursory argument that the *qui tam* provisions of the FCA violate Article II of the Constitution. ECF No. 80 at 25. The Court can summarily reject this purported constitutional challenge because it is conclusory and unsupported. *E.g., Clay v. Holy Cross Hosp.*, 253 F.3d 1000, 1002 n.1 (7th Cir. 2001) (“[P]erfunctory and undeveloped arguments, and arguments that are unsupported by pertinent authority, are waived.”); *Wilson v. City of Mission, Tex.*, No. 7:18-CV-399, 2020 WL 2079359, at *10 (S.D. Tex. Apr. 29, 2020) (“This Court is entitled to have issues clearly defined; arguments asserted without citation to authority or left undeveloped are waived.”).

In any event, Defendants’ position lacks merit. In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, the Supreme Court upheld the constitutionality of the *qui tam* provisions of the FCA. 529 U.S. 765 (2000). The Supreme Court noted the “long tradition . . . in England and the American Colonies” of *qui tam* provisions that authorized private persons to bring suit to recover damages suffered by the United States and observed that “the First Congress enacted a considerable number of informer statutes” similar in structure to the FCA. *See id.* at 774, 776. Shortly after that decision, the Fifth Circuit, sitting en banc, applied the Supreme Court’s rationale to conclude that the *qui tam* provisions of the FCA did not violate Article II. *Riley v. St. Luke’s Episcopal Hosp.*, 252 F.3d 749, 752 (5th Cir. 2001) (en banc) (“Although the Court in *Stevens* expressed no opinion regarding the role of history in evaluating the Article II Take Care and

Appointments Clauses questions, we are persuaded that it is logically inescapable that the same history that was conclusive on the Article III question in *Stevens* with respect to qui tam lawsuits initiated under the FCA is similarly conclusive with respect to the Article II question concerning this statute.”). Like *Riley*, other Circuits have unanimously rejected challenges to the FCA’s constitutionality. *See United States ex rel. Stone v. Rockwell Int’l Corp.*, 282 F.3d 787, 804–05 (10th Cir. 2002); *United States ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1041 (6th Cir. 1994); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 757–59 (9th Cir. 1993); *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1154–55 (2d Cir. 1993).

The sole authority cited by defendants in support of their argument is a concurrence and a solo dissent in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, in which three justices of the Supreme Court opined that the Court should consider whether the *qui tam* provisions of the FCA violate Article II of the Constitution.¹ 599 U.S. 419 (2023). This is not a development sufficient to raise substantial doubt that every Court of Appeals to confront this issue has decided it wrongly. To the contrary: while three justices may have advocated for a constitutionality review, six justices did not.

As an initial matter, courts “should invalidate an act of Congress only ‘for the most compelling constitutional reasons’” and “are obliged whenever ‘fairly possible’ to interpret

¹ Justice Thomas stated in dissent—joined by no other member of the Court—that “there is good reason to suspect that Article II does not permit private relators to represent the United States’ interests in FCA suits.” *Polansky*, 599 U.S. at 451 (Thomas, J., dissenting). Justice Kavanaugh, joined by Justice Barrett, stated in concurrence that “the Court should consider the competing arguments on the Article II issue in an appropriate case,” but both justices joined the majority opinion “in full.” *Id.* at 442 (Kavanaugh, J., concurring).

a statute in a manner that renders it constitutionally valid.” *Kelly*, 9 F.3d at 747 (quoting *Mistretta v. United States*, 488 U.S. 361, 384 (1989), and *Comm’cns Workers of Am. v. Beck*, 487 U.S. 735, 762 (1988)). Moreover, the Fifth Circuit’s conclusion that the FCA does not violate Article II is correct. The Court’s analysis focused on the fact that the United States retains significant control over *qui tam* suits in which it does not intervene. *Riley*, 252 F.3d at 753–57. Other courts of appeals addressing the FCA’s constitutionality have focused on the government’s significant power in declined suits as well. See *Kelly*, 9 F.3d at 753–55; *Taxpayers Against Fraud*, 41 F.3d at 1041; *Kreindler & Kreindler*, 985 F.2d at 1155. This is because in determining whether legislation “disrupts the proper balance between the coordinate branches, the proper inquiry focuses on the extent to which it prevents the Executive Branch from accomplishing its constitutionally assigned functions.” *Nixon v. Administrator of Gen. Servs.*, 433 U.S. 425, 443 (1977). The unique structure of the FCA ensures that regardless of whether the United States intervenes in a given suit, a relator’s conduct of *qui tam* litigation does not prevent the Executive Branch from carrying out its constitutional functions—a point on which courts have long agreed.

Defendants’ suggestion to the contrary notwithstanding, the Supreme Court’s recent *Polansky* decision bolsters the analysis set forth by the Fifth Circuit in *Riley* and all the other federal courts of appeals that have addressed this issue, by underscoring the broad power the government wields to intervene in and dismiss *qui tam* suits. The Court first held that the government may intervene in a *qui tam* suit at any point in the case, agreeing with the lower court that the “good cause” standard for intervention is “neither a burdensome nor unfamiliar obligation,” but simply requires the government to proffer a

“legally sufficient reason,” such as intervention for the purpose of moving to dismiss. *See Polansky*, 599 U.S. at 429 n.2, 432–433. The Court then confirmed that once the government has intervened, it assumes “primary responsibility” over the suit, rejecting the relator’s (and dissent’s) argument that the government “take[s] a back seat” to the relator. *Id.* at 435, 437. Finally, the Court held that when the government moves to dismiss a *qui tam* suit, a district court should grant the motion “in all but the most exceptional cases.” *Id.* at 437. The Court explained that the government’s views on dismissal “are entitled to substantial deference” and should lead to dismissal “even if the relator presents a credible assessment to the contrary.” *Id.* at 437–38. Thus, any concerns that the *qui tam* mechanism in the FCA prevents the Executive Branch from accomplishing its constitutionally assigned functions are diminished, not heightened, by the holding in *Polansky*.

CONCLUSION

For the foregoing reasons, the United States respectfully submits that proof of FCA liability for claims that arise out of kickbacks does not require a showing that the kickback was the but-for cause of submission of the false claim. In addition, if the Court addresses the issue, the United States respectfully asks the Court to hold, consistent with binding Fifth Circuit precedent, that the FCA does not violate Article II of the United States’ constitution. And if the Court dismisses Relator’s Complaint because it is inadequately pleaded, the United States requests that such dismissal be without prejudice to the United States. *See, e.g., United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455–56 (5th Cir. 2005).

Respectfully submitted,

BRIAN M. BOYNTON
PRINCIPAL DEPUTY ASSISTANT ATTORNEY
GENERAL

LEIGHA SIMONTON
UNITED STATES ATTORNEY

/s/ Richard J. Guiltinan
RICHARD J. GUILTINAN
Assistant United States Attorney
Texas Bar No. 24074332
1100 Commerce Street, Third Floor
Dallas, Texas 75242
Telephone: 214-659-8600
Facsimile: 214-659-8807
Email: richard.guiltinan@usdoj.gov

JAMIE ANN YABELBERG
DAVID B. WISEMAN
DAVID G. MILLER
Attorneys, Civil Division
U.S. Department of Justice
175 N Street N.E.
Washington, D.C. 20002
Telephone: 202-305-3231
Email: David.G.Miller@usdoj.gov

Attorneys for the United States of America

CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2024, I electronically submitted the foregoing document with the clerk of the court for the U.S. District Court, Northern District of Texas, using the electronic case filing system and served upon all opposing parties, or their attorneys of record, by electronic delivery on this date.

/s/ Richard J. Guiltinan
Richard J. Guiltinan
Assistant United States Attorney